INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

DRAFT CONSENSUS GUIDELINE

ORGANISATION OF THE COMMON TECHNICAL DOCUMENT FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

Released for Consultation

at *Step 2* of the ICH Process

on 20 July 2000

by the ICH Steering Committee

At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Steering Committee to the regulatory authorities of the three ICH regions (the European Union, Japan and the USA) for internal and external consultation, according to national or regional procedures.

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OBJECTIVE OF THE GUIDELINE

This guideline presents the agreed upon common format for the preparation of a well-structured Common Technical Document for applications that will be submitted to Regulatory Authorities. A common format for the technical documentation will significantly reduce the time and resources needed to compile applications for registration of human pharmaceuticals and will ease the preparation of electronic submissions. Regulatory reviews and communication with the applicant will be facilitated by a standard document of common elements. In addition, exchange of regulatory information between Regulatory Authorities will be simplified.

BACKGROUND

Through the ICH process, considerable harmonisation has been achieved among the three regions in the technical requirements for the registration of pharmaceuticals for human use. However, there is no harmonisation of the organisation of the registration documents. Each region has its own requirements for the organisation of the technical reports in the submission and for the preparation of the summaries and tables. In Japan, the applicants must prepare the GAIYO, which organises and presents a summary of the technical information. In Europe, Expert Reports and Tabulated Summaries are required, and Written Summaries are recommended. The US FDA has guidance regarding the format and content of the New Drug Application. To avoid the need to generate and compile different registration dossiers, this guideline describes a format for the Common Technical Document that will be acceptable in all three regions.

SCOPE OF THE GUIDELINE

This guideline primarily addresses the organisation of the information to be presented in Registration Applications for new pharmaceuticals (including biotechnology-derived products). With appropriate modifications, the guideline can also be applied to abbreviated or abridged applications and variations.

This guideline is not intended to indicate what studies are required. It merely indicates an appropriate format for the data that have been acquired.

Applicants should not modify the overall structure of the Common Technical Document as outlined in the guideline. However, within the overall structure, applicants can modify the format if needed to provide the best possible presentation of the information, in order to facilitate the understanding and evaluation of the results.

GENERAL PRINCIPLES

Throughout the Common Technical Document, the display of information should be unambiguous and transparent, in order to facilitate the review of the basic data and to help a reviewer become quickly oriented to the application contents.

Text and tables should be prepared using margins that allow the document to be printed on both A4 paper (EU and Japan) and 8.5 x 11" paper (US). The left-hand margin should be sufficiently large that information is not obscured by the method of binding. Font sizes for text and tables should be of a style and size that are large enough to be easily legible, even after photocopying.

ORGANISATION OF THE COMMON TECHNICAL DOCUMENT

It is recommended that the Common Technical Document be organised into five major sections, or modules. Modules II, III, IV, and V are intended to be common for all regions. Conformance with this guideline should ensure that these four modules are provided in a format acceptable to the Regulatory Authorities.

Module I. Administrative Information and Prescribing Information

This section should contain documents specific to each region; for example, application forms or the proposed label for use in the region. The content and format of this module can be specified by the relevant Regulatory Authorities.

Module II. Common Technical Document Summaries

Module II should provide Overall Summaries of the Quality, Nonclinical, and Clinical information in the Common Technical Document. This should be followed by the Nonclinical Written Summaries, the Nonclinical Tabulated Summaries, and the Written Summary of Human Studies and Experience.

Module II should begin with a general introduction to the pharmaceutical, including its pharmacologic class and mode of action, and its proposed clinical use. In general, the Introduction should not exceed one page.

Module III. Quality

The information on Quality should be presented in the structured format described in Guideline M4Q.

Module IV. Nonclinical Study Reports

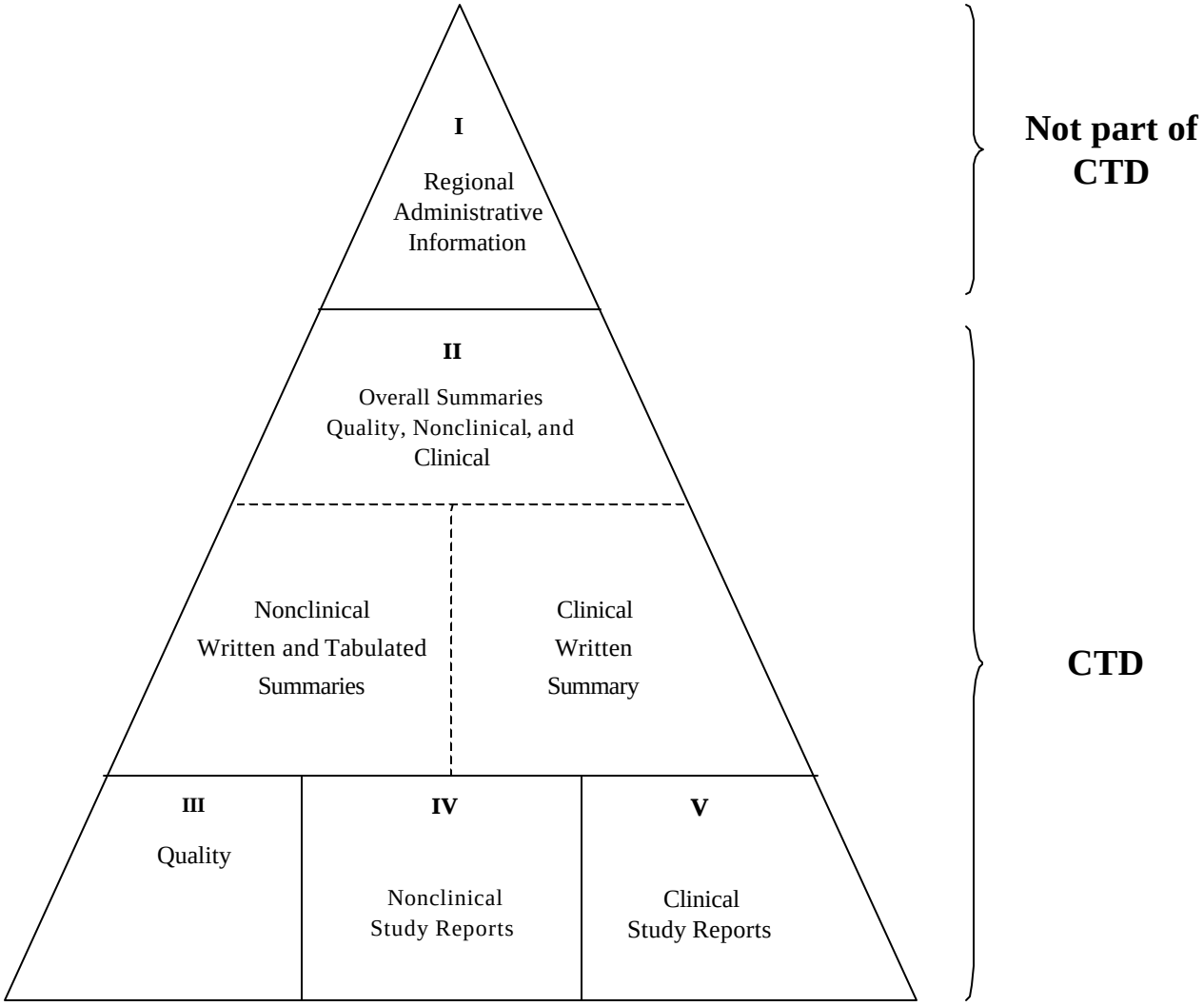
The nonclinical study reports should be presented in the order prescribed in Guideline M4S.

Module V. Clinical Study Reports

The human study reports and related information should be presented in the order prescribed in Guideline M4E .

The overall organisation of the Common Technical Document is presented on the following pages.

Diagrammatic Representation of the ICH Common Technical Document



ORGANISATION OF THE COMMON TECHNICAL DOCUMENT FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

Module I: Administrative Information and Product Labeling

- A. Module I Table of Contents
- B. Documents specific to each region; for example, application forms, prescribing information.

Module II: Common Technical Document Summaries

- A. Overall Common Technical Document Table of Contents
- B. Overall Summaries
  1. Introduction
  2. Quality Overall Summary
  3. Nonclinical Overall Summary
  4. Clinical Overall Summary
- C. Nonclinical Summaries
  1. Pharmacology
     a. Written Summary
     b. Tabulated Summary
  2. Pharmacokinetics
     a. Written Summary
     b. Tabulated Summary
  3. Toxicology
     a. Written Summary
     b. Tabulated Summary
- D. Clinical Written Summary
  1. Biopharmaceutics and Associated Analytical Methods
  2. Clinical Pharmacology
  3. Clinical Efficacy
  4. Clinical Safety
  5. Synopses of Individual Studies

Module III: Quality

- A. Table of Contents

B. Body of Data

Module IV: Nonclinical Study Reports

A. Table of Contents

B. Study Reports

C. Key Literature References

Module V: Clinical Study Reports

A. Table of Contents

B. Study Reports

C. Key Literature References